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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,215	10/26/2001	Kevin K. Liu	PC11053AMAG	8104

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EXAMINER	
COLEMAN, BRENDA LIBBY	
ART UNIT	**PAPER NUMBER**
1624	

DATE MAILED: 12/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/006,215	LIU ET AL.	
	Examiner	Art Unit	
	Brenda L. Coleman	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,12,13,18-20,24,27 and 29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,12,13,18-20,24,27 and 29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-6, 12, 13, 18-20, 24, 27 and 29 are pending in the application.

This action is in response to applicants' amendment dated September 19, 2005. Claims 1, 2, 18 and 20 have been amended.

Response to Arguments

Applicant's arguments filed September 19, 2005 have been fully considered with the following effect:

1. The applicants' amendments are sufficient to overcome the 35 U.S.C. § 102, anticipation rejection labeled paragraph 1 maintained in the last office action, which is hereby **withdrawn**.

2. The applicants' amendments are sufficient to overcome the 35 U.S.C. § 103, obviousness rejection labeled paragraph 2 maintained in the last office action, which is hereby **withdrawn**.

3. With regards to the 35 U.S.C. § 112, first paragraph rejection of claim 27 in the last office action, applicants' state that claim 27 identifies a particular group of diseases or conditions, i.e. obesity, diabetes, depression, anxiety and neurodegeneration in a mammal. The applicants state that these diseases are known by one skilled in the art to be impacted by glucocorticoid modulation. However, neurodegeneration is a class of diseases and/or conditions and not a specific disease or condition as defined in the specification, i.e. neurodegeneration (for example, Alzheimer's disease and Parkinson's disease). Neurodegeneration includes more than Alzheimer's disease and Parkinson's disease such as global cerebral ischemia, amyotropic lateral sclerosis, stroke and cystic

periventricular leukomalacia. While the compounds of the present Formula (I) may have been shown to have a positive effect in the treatment of Alzheimer's disease and Parkinson's disease, this does not provide enablement for the treatment of the diseases and disorders as claimed herein. Evidence must demonstrate that the modulation of glucocorticoid and neurodegenerative diseases as a class are treatable.

It has been recited in claim 27, a method for the treatment of a glucocorticoid receptor-mediated disease or condition which is selected from the group consisting of obesity, diabetes, depression, anxiety and neurodegeneration. There is no such an agent, which can treat neurodegenerative disorders generally. That is because neurodegenerative disorders are extremely varied in origin and nature of effect. The origin and the nature of many neurodegenerative disorders such as Huntington's disease, Pick's disease, Frontotemporal dementia, Cerebro-Oculo-Facio-Skeletal (COFS) syndrome (cranofacial and skeletal abnormalities), Motor neuron disease (muscle weakness), Corticobasal ganglionic degeneration, Creutzfeldt-Jacob disease (fatal disease), Dementia with Lewy bodies, and Progressive supranuclear palsy Dementia are different one from the other. Many neurodegenerative disorders are untreatable to this day.

The symptoms and nature of these diseases are also different one from the other. It can be shown that many of these neurodegenerative disorders have different origin and nature of effect. Some neurodegenerative disorders are hereditary (Charcot-Marie-Tooth disease). Many neurodegenerative disorders vary in how they affect the body and its functions. Diseases such as Cerebral palsy, and Parkinson's disease

affect the movement of the patient. Diseases such as Alzheimer's disease affect the memory of the patient.

Where the utility is unusual or difficult to treat or speculative, the examiner has authority to require evidence that tests relied upon are reasonably predictive of in vivo efficacy by those skilled in the art. See In re Ruskin, 148 USPQ 221; Ex parte Jovanovics, 211 USPQ 907; MPEP 2164.05(a).

Patent Protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. Tossing out the mere germ of an idea does not constitute enabling disclosure. Genentech Inc. v. Novo Nordisk 42 USPQ2d 1001.

Claim 27 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for reasons of record and stated above.

4. The applicants' amendments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejections labeled paragraph 4 in the last office action, which are hereby **withdrawn**.

5. With regards to the 35 U.S.C. § 102, anticipation rejection of claims 1 and 3-6 of the last office action, the applicant's arguments have been fully considered but are not found persuasive. The applicants stated that Murry fails to anticipate the subject matter of independent claim 1 and dependent claims 3-6 because of the proviso where when R_1 is $-C\equiv C-CH_3$, R_2 is phenyl and R_3 is hydrogen, then R_4 is other than $-(CH_2)_2-N(CH_3)_2$

or -$(CH_2)_3$-$N(CH_3)_2$. However, it is the definition of R_1 where **R_1 is -CF_3**; R_2 is phenyl; R_3 is methyl and R_4 is -$(CH_2)_2$-$N(CH_3)_2$ as shown by the example XVII.

Claims 1 and 3-6 are rejected under 35 U.S.C. 102(e) as being anticipated by Murry et al., U.S. 2002/0087005, for reasons of record and stated above.

6. With regards to the obviousness-type double patenting rejection of claims 1-6, 12, 13, 18-20, 24, 27 and 29 labeled paragraph 6 of the last office action, the applicant's arguments have been fully considered but are not found persuasive. The applicants stated that the claims of U.S. Patent No. 6,699,893 are such that Z is C_1-C_6 alkyl, C_2-C_6 alkenyl, or C_2-C_6 alkynyl. The definition of Z in claim 1 is acknowledged, however, the definition of Z in claims 4 and 27 is –(C_0-C_2)alkyl and thus when R_{10} is -O-Z-(CO)-NH-(C_0-C_3)alkyl-$NR_{12}R_{13}$ results in the substituent of the instant invention 0O-C(O)-NR_3R_4.

Claims 1-6, 12, 13, 18-20, 24, 27 and 29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 6,699,893, for reasons of record and stated above.

7. With regards to the obviousness-type double patenting rejection of claims 1-6, 12, 13, 18-20, 24, 27 and 29, labeled paragraph 7) in the last office action, the applicants' failed to comment on this rejection.

Claims 1-6, 12, 13, 18-20, 24, 27 and 29 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-34 of copending Application No. 10/721,318, for reasons of record and stated above.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

In view of the amendment dated September 19, 2005, the following new grounds of rejection apply:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-6, 12, 18 and 27 are rejected under 35 U.S.C. 1 12, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the invention, at the time the application was filed, had possession of the claimed invention. The addition of hydrogen in the definition of R_5 and R_6 is not described in the specification with respect to the genus of formula I.

Applicant is required to cancel the new matter in the reply to this Office action.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

9. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reason(s) apply:

a) Claim 2 is vague and indefinite in that it is not known what is meant by the definition of R_1 where R_1 is -C≡C-CH_3-CF_3.

b) Claim 2 is vague and indefinite in that it is not known what is meant by the definition of R_1 where R_1 is -CF3.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brenda Coleman

Brenda Coleman
Primary Examiner Art Unit 1624
December 11, 2005